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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,716	11/30/2000	David F. O'Brien	15907-0022	4843

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No. 09/728,716	Applicant(s) O'BRIEN ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *8-19-05 and 8-31-05*.

2. ☒ The allowed claim(s) is/are *1,4-8 and 17-37*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 7-8-02, 6-14-05 9-7-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *8-31-05* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/ S Kishore

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jim Fox on 8-31-05.

The application has been amended as follows:

Claims 1, 20, 24, 27, 32 and 37 have been amended as follows:

Claim1. (Currently amended) An unpolymerized ionizing radiation sensitive ~~gel-like lamellar~~ liposome delivery system at room temperature, produced by the method of: ~~comprising~~

(i) selecting a stable liposome-forming lipid or lipids, and ~~discrete domains of~~ an ionizing radiation polymerizable colipid or colipids, wherein said polymerizable colipid comprises a polymerizable group selected from the group consisting of diacetylenyl, acryloyl, methacryloyl, dienoyl, dienyl, sorbyl, muconyl, styryl, vinyl, and lipoyl;

(ii) drying the lipids and colipids that comprise the liposome;

(iii) hydrating said lipids and colipids with a buffer comprising releasable agents to be encapsulated or associated in a desired molar ratio to form liposomes at a temperature which enables the colipids to cluster in discrete domains in said liposomes; and

(iv) purifying the liposomes,

~~and further comprising a releasable agent and~~ wherein after administration to a patient the colipids ~~are~~ in said liposomes remain clustered in discrete domains.

Claim 20. (Currently amended) A method of treating a condition responsive to a therapeutic agent, comprising the steps of:

(i) administering to a patient a pharmaceutical composition comprising an unpolymerized ionizing radiation sensitive ~~gel-like lamellar~~ liposome delivery system of claim 1, comprising stable liposome-forming lipids and discrete domains of ionizing radiation polymerizable colipids, wherein said polymerizable colipid comprises a polymerizable group selected from the group consisting of diacetylenyl, acryloyl, methacryloyl, dienoyl, dienyl, sorbyl, muconyl, styryl, vinyl, and lipoyl; and further comprising a releasable therapeutic agent;

(ii) subjecting the patient to ionizing radiation to polymerize a fraction of said colipid, destabilize the liposome and release the therapeutic agent.

Claim 24. (Currently amended) A method of diagnosing the presence or progression of a disease, comprising the steps of:

(i) administering to a patient a diagnostic composition comprising an unpolymerized ionizing radiation sensitive ~~gel-like lamellar~~ liposome delivery system of claim 1, comprising stable liposome-forming lipids and discrete domains of ionizing radiation polymerizable colipids, wherein said polymerizable colipid comprises a polymerizable group selected from the group consisting of diacetylenyl, acryloyl, methacryloyl, dienoyl,

dienyl, sorbyl, muconyl, styryl, vinyl, and lipoyl; and further comprising a releasable diagnostic agent,

(ii) subjecting the patient to ionizing radiation in order to destabilize the liposome delivery system and release the diagnostic agent; and

(iii) diagnosing said disease through the use of molecular imaging techniques.

Claim 27. (Currently amended) A method of producing an ionizing radiation sensitive liposome delivery system comprising the steps of:

(i) selecting a stable liposome-forming lipid or lipids, and an ionizing radiation polymerizable colipid or colipids, wherein said polymerizable colipid comprises a polymerizable group selected from the group consisting of diacetylenyl, acryloyl, methacryloyl, dienoyl, dienyl, sorbyl, muconyl, styryl, vinyl, and lipoyl;

(ii) drying the lipids and colipids that comprise the liposome,

(iii) hydrating said lipids and colipids with a buffer, comprising agents to be encapsulated or associated in a desired molar ratio to ~~create hydrated bilayers~~ form liposomes at a temperature which enables the colipids to cluster in discrete domains in said liposomes; and,

~~(iv) converting said bilayers into liposomes; and~~

(iv) purifying the liposomes

to form an unpolymerized radiation sensitive ~~gel-like lamellar~~ liposome delivery system

at room temperature and wherein after administration to a patient the colipids ~~are~~ in said liposomes remain clustered in discrete domains.

Claim 32. (Currently amended) A radiation sensitive liposome delivery system that can be targeted to a tumor site through attachment of at least one targeting peptide to the liposome of claim 1 ~~10~~.

Claim 37. (Currently Amended) An unpolymerized ionizing radiation sensitive ~~gel like lamellar~~ liposome delivery system at room temperature, produced by the method of: ~~comprising~~

(i) selecting a stable liposome-forming lipid or lipids, a steric stabilizer or stabilizers, and ~~discrete domains of~~ an ionizing radiation polymerizable colipid or colipids wherein said polymerizable colipid comprises a polymerizable group selected from the group consisting of diacetylenyl, acryloyl, methacryloyl, dienoyl, dienyl, sorbyl, muconyl, styryl, vinyl, and lipoyl;

(ii) drying the lipids, stabilizers and colipids that comprise the liposome,

(iii) hydrating said lipids and colipids with a buffer comprising releasable agents to be encapsulated or associated in a desired molar ratio to form liposomes at a temperature which enables the colipids to cluster in discrete domains in said liposomes; and

(iv) purifying the liposomes,

~~and further comprising a steric stabilizer and a releasable agent~~ wherein after administration to a patient the colipids in said liposomes remain clustered in discrete domains.

2. The following is an examiner's statement of reasons for allowance: the prior art on record neither teaches nor suggests a liposome delivery system at room temperature comprising a lipid and discrete domains of ionizing radiation polymerizable colipid.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK

Continuation of Substance of Interview including description of the general nature of what was discussed: The initial conversation on 8-23-05 was with Leslie Mooi and that on 8-31-05 was with Jim Fox. The examiner informed that since 'gel-like' introduced in the independent claims does not appear to have support in the specification. The examiner also suggested that the claims be recited as product by process claims as agreed upon in the interview dated 8-10-05 to differentiate from Lamparski. The attorney will e mail the amendments which will be converted into an examiner's amendment. .